IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	Unassigned	Confirmation No. Unassigned
Applicant	Wing CHEUNG et al.	
Filed	24 March 2004	
TC/Art Unit	Unassigned	
Examiner	Unassigned	
Docket No.	38081-00036	
Customer No.	23767	

PETITION TO MAKE SPECIAL
UNDER 37 C.F.R. § 1.102 AND M.P.E.P. § 708.02(X)

Mail Stop Patent Application
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.102, Applicants hereby petition the Director of the United States Patent and Trademark Office to make the referenced application special and receive accelerated examination on the basis that the invention relates to cancer treatment as delineated under M.P.E.P. § 708.02(X).

Pursuant to M.P.E.P. § 708.02(X), the present invention contributes to the treatment of cancer. *See, e.g.,* claims 204-323. Specifically, independent claims 204, 234, 264, and 294 contribute to the treatment of cancer through methods for optimizing, selecting and administering erythropoietin (EPO) dosage regimens. EPO administration contributes directly to the treatment of cancer, for example, by its use to correct anemia associated with platinum-based cancer chemotherapy. *See, e.g.,* application at page 4, lines 14-16. *See also id.* at pages 59-76 and 82-85.

Notably, deficient (or inefficient) EPO production relative to hemoglobin level is associated with certain forms of anemia, and these include malignancy. *Id.* at page 3, lines 27-31. Presently, there are a number of disadvantages associated with the standard EPO dosage regimen administered to patients, for example, in specific indications such as cancer. *Id.* at page 4, line 32 – page 5, line 1. "Thus, it remains an important goal to change the currently approved dosing schedule to a more convenient dosing schedule and regimen." *Id.* at page 5, lines 1-3. "[A] less frequent administration will improve user acceptance and convenience." *Id.* at page 5, lines 3-4. The significance of EPO administration for cancer

treatment is abundantly clear from those dependent claims specifically defining the use of these claimed methods for the optimization of EPO dosing regimens for patients suffering from cancer chemotherapy related anemia. *See, e.g.,* claims 223, 226, 253, 256, 283, 286, 313, and 316. "In clinical trials, Epoetin alfa has been evaluated. . .in patients with various anemic conditions" and "Epoetin alfa may be used to correct anemia in other patient groups including anemia associated with platinum-based cancer chemotherapy . . . ." Application at page 4, lines 9-10 and lines 14-16, respectively. "The present invention can address the requirements of patients that may have deficient or inefficient EPO production relative to hemoglobin level, which may be associated with certain forms of anemia. These may include. . .platinum based cancer chemotherapy related anemia. . . ." *Id.* at page 10, lines 6-10.

The significance of proper EPO administration for cancer treatment and therapy is also abundantly clear due to the correlation of anticancer drug therapy and anemia in chronic disease. For example:

> Erythroid hypoplasia of the bone marrow, decreased RBC survival, and decreased reticulocytosis are reported (*see, e.g.,* Abels, 1992. *Semin. Oncol.* 19:29-35) to be some of the possible causes of anemia in chronic disease. Anticancer drug therapy is also thought to be one of the principle causes of anemia in these patients. (*see, e.g.,* Matsumoto, *et al.*, 1990. *Br. J. Pharmacol.* 75:463-68.) A reduction in the Ks value by 1/3rd, indicating a lowered intrinsic production rate of cells and/or a lower S_{max} could explain the diminished responses as seen in the simulations. Cancer patients have baseline EPO concentrations, which are higher than normal, but inappropriately low for the degree of anemia. (*see, e.g.,* Case, *et al.*, 1993. *Natl. Cancer Inst.* 85:801-806 and Miller, *et al.,* 1990. *N. Engl. J. Med.* 322:1689-99. The baseline EPO concentrations are reported to range from lower than 40 to higher than 500 U/L (*see, e.g.,* Ludwig, *et al.*, 1994. *Blood* 84:1056-63, Case *et al., supra,* Abels, *supra,* and Miller *et al., supra*) depending on the severity and type of anemia associated with the cancer and chemotherapy. Baseline EPO levels greater than 500 IU/l have been reported to indicate unresponsiveness to rHuEPO therapy. (*see, e.g.,* Ludwig *et al., supra.*)

Id. at page 83, line 22 – page 84, line 4.

Accordingly, Applicants respectfully request that this Petition To Make Special be granted and that the pending claims be examined and allowed as quickly as possible.

Pursuant to 37 C.F.R. § 1.102(d), Applicants enclose a check including the $130.00 fee as required by 37 C.F.R. § 1.17(h). In the event any additional fees are due in connection with this paper, please charge the undersigned's Deposit Account No. 50-1067.

Respectfully submitted,

24 March 2004

Don J. Pelto
Reg. No. 33,754

Preston Gates Ellis & Rouvelas Meeds LLP
1735 New York Ave., N.W.
Washington, DC 20006
Telephone: (202) 628-1700
Facsimile: (202) 331-1024